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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/446,415 07/19/00 BEAMER

L 11034US02/0

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HM12/0424

EXAMINER

MARSCHEL, A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED:

8

04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.

09/446,415

Applicant(s)

Beamer et al.

Examiner

Ardin Marsch I

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Jan 11, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above, claim(s) 7-14, 24, and 25 is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-6 and 16-23 is/are rejected.

7) ☒ Claim(s) 15 is/are objected to.

8) ☒ Claims 1-25 are subject to restriction and/or election requirements.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other: \_\_\_\_\_

Applicants' election of Specie A (claims 1-6 and 15-23) in Paper No. 7, filed 1/11/01, is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because only 2 sequences are listed in the present sequence listing whereas 4 more sequences which are not in said sequence listing are disclosed in the specification on page 44 as well as added sequences in Figures 5A and 5B.

Applicants are reminded that a new computer readable form sequence listing and paper copy for replacing the present paper copy in the specification and a statement under 37 CFR § 1.821(f) is required. Applicants are reminded that Figures are not required to contain SEQ ID NOs per se but that the SEQ ID NOs then must be listed in the Brief Description of the Figures for sequences in each Figure. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to

this Office action.

Claim 15 is objected to under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim cannot properly depend from another multiple dependent claims See M.P.E.P. § 608.01(n). Accordingly, claim 15 is not been further treated on the merits.

Claims 1-6 and 16-23 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the 456 amino acid BPI protein of SEQ ID NO: 1, does not reasonably provide enablement for any BPI analog or variant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

It is noted that BPI is described in the instant application as being characterized by a myriad of biological activities. None of these activities, however, have been enabled as to assay procedures by which to determine whether a protein is BPI protein or not. Thus, a protein which is a analog or variant or a fragment of BPI cannot be determined as to whether it is properly a BPI protein without an activity assay. The determination of a protein being a BPI protein is required, for example, in instant claim 1. Thus the assaying of protein activity for BPI activity is deemed essential subject matter for this determination. Such essential subject matter cannot be incorporated by reference to a printed publication or foreign patent document. See the below given paragraph summarizing this issue regarding incorporation by reference. Another issue in support of this rejection is that many of the instant claim refer to amino acid positions which are only enabled, or make sense, if SEQ ID NO: 1 BPI protein is being utilized.

The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required

to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157; *In re Hawkins*, 486 F.2d 579, 179 USPQ 163; *In re Hawkins*, 486 F.2d 577, 179 USPQ 167.

Claims 1-6 and 16-23 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Given the above noted myriad of BPI protein activities, the metes and bounds of which of these activities should define what is and what is not BPI protein are vague and indefinite.

Claim 4 is vague and indefinite in citing Table 31 whereas confusingly Table 31 has not been found in the instant application.

Claim 22 is vague and indefinite in citing Figures 2-20 whereas only figures 1A through 6 are in the instant file. Where are Figures 7-20?

Claims 1-6 provide for the use of atomic coordinates of BPI etc., but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicants are intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-6 are rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The disclosure is objected to because of the following informalities:

It is noted that the Figure designations on pages 14-15 of the specification differ from the actual Figures in that 1A is in the Figures whereas confusingly 1(A) is set forth on said page 14, for example.

Correction is required.

No claim is allowed.


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703)308-0196.

April 20, 2001

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER